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09/807,657	04/16/2001	Nathalie Garcon	B 45158	2235

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/23/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,657

Applicant(s)

GARCON, NATHALIE

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-37,39-62,71-116,118 and 119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-37,42,44-62,115,116 and 118 is/are allowed.
- 6) ☒ Claim(s) 39-41,43,71-114 and 119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. Claims 32-37, 39-62, and 71-116, 118, and 119 are currently pending in the present application. Claims 32-37, 39-45, 47, 50-55, 57-62, 71-114, 116, and 119 of the currently pending claims were rejected in the prior action. The subject matter of claims 46, 49, 53, 54, 56, 115, and 118 was indicated to be allowable.
2. In the Response filed on June 30, 2003 (C.O.M. June 26, 2003), claims 32, 39-42, 44, 47, 71-92, and 116 were amended, and claim 117 was cancelled.
3. This action is being made Non-Final because new issues and rejections are being raised.

Specification

4. **(Prior Objection-Maintained)** The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. The specification does not provide any antecedent basis for the claim limitation regarding immunostimulants "wherein the immunostimulant is not a saponin derived from the bark of Quillaja Saponaria Molina." Note- this is not a lack of written description support rejection. It is required however, that the description of the application provide antecedent basis for claim language. See, 37 CFR 1.75 (d) (1) and MPEP 608.01 (o). Again, it is suggested that a sentence such as the following be inserted at the end of the last paragraph of page 5: -- The immunostimulants of the vaccines of the present invention may be any immunostimulant, including those listed above, or may be any

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immunostimulant wherein the immunostimulant is not a saponin derived from the bark of Quillaja Saponaria Molina. -- Such an insertion would overcome the present objection.

5. **(New Objection)** The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not appear to contain antecedent basis for the claim language identifying LnRH(GnRH) as an antigen. This objection may be overcome by either pointing out where support for the claim language is, or by amending the specification to provide such antecedent basis.

6. **(New Objection)** The disclosure is objected to because of the following informalities: on page 9, the application refers to vaccines comprising the component Hib by its acronym, but does not identify the vaccine component by its full name (Haemophilus influenzae b).

Appropriate correction is required.

7. **(Prior Objection- Withdrawn)** The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The specification did not provide any antecedent basis for the claim limitation "characterized in that said metallic salt is substantially free of monophosphoryl lipid A, or [a] derivative thereof." In view of the amendments of the claims and the specification, the objection is withdrawn.

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Claim Objections

8. **(New Objection)** Claims 71-81 are objected to because of the following informalities: These claims each identify Hib and LnRH(GnRH) as antigens that may be used in the claimed invention. However, the claims do not first identify the antigen by its complete name prior to using its acronym. Appropriate correction is required.

9. **(Prior Objection-Withdrawn)** Claim 47 was objected to because of the following informalities: the last phrase of the claim should read "or *a* derivative thereof," rather than "or derivative thereof." In view of the amendments to the claim rendering this objection moot, the objection is withdrawn.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection-Withdrawn)** Claims 32-35, 39-43, 71, 72, 82, 83, 93, 94, 104, 105, 116, and 117 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims were rejected because there is no support in the specification as

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filed for the assertion that an immunostimulant may itself be an antigen. In view of the amendments to the claims, the rejection is withdrawn.

12. **(Prior Rejection-Withdrawn)** Claims 32-40, 42, 43, 116, and 117 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising an immunostimulant and an antigen, does not reasonably provide enablement for such compositions wherein said immunostimulant (first antigen) and said (second) antigen are the same. In view of the amendments to the claims, the rejection is withdrawn.

13. **(Prior Rejection-Withdrawn)** Claims 32-35, 39-43, 71, 72, 82, 83, 93, 94, 104, and 105 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims lacked support in the application as filed because the applicant has not demonstrated that any of these antigens may also act as immunostimulants. In view of the amendment to the claims, the rejection is withdrawn.

14. **(Prior Rejection-Withdrawn)** Claims 32-35, 39-43, 71, 72, 82, 83, 93, 94, 104, and 105 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising an immunostimulant and an antigen, does not reasonably provide enablement for such compositions wherein said immunostimulant (first antigen) and said

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(second) antigen are the same In view of the amendment to the claims, the rejection is withdrawn.

15. **(Prior Rejection- Withdrawn)** Claims 39, 41-45, 50-55, 60-62, 71-74, 79-85, 90-96, 101-107, 112-114, 117, and 119 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vaccines, and methods of making the claimed vaccine composition, wherein the antigen is adsorbed to a separate metallic salt, does not reasonably provide enablement for such compositions where the antigen is not so adsorbed. In view of the Applicant's arguments to the rejection, it is hereby withdrawn.

16. **(New Rejection)** Claims 41, 43, 71-81, and 93-114 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for vaccines against all of the identified pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. These claims read on vaccines comprising the claimed immunostimulant/metal salt complex. The claims describe the claimed vaccines as comprising antigens of a number of difference pathogenic sources. However, for several of these pathogenic sources, no vaccines are currently known or recognized. See e.g., Perbandt et al. JBC Papers in Press, Sept 12, 2003 (indicating on page 2 that there is currently no vaccine available against Plasmodium falciparum); U.S. Patent 6,544,527, col. 2, lines 29-30 (indicating that there is currently no vaccine or cure for AIDS); and de Swart et al., J Virol 76(22): 11561-69 (teaching that there are no vaccines currently licensed

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against respiratory syncytial virus). Thus, the Applicant is not enabled for the claimed compositions as vaccines. It is noted that the Applicant would be enabled for immunogenic compositions.

17. **(New Rejection)** Claims 39-41, 43, and 119 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims read on vaccines, and methods of making such, wherein the vaccines comprise an immunostimulant adsorbed onto a salt particle, and an antigen. The specification and the original claims disclose the claimed invention as comprising immunostimulants adsorbed to a metallic salt particle that is substantially free of antigen. See pages, 2-3, and original claims 1 and 8. The identified claims do not require that the salt particles to which the immunostimulant is adsorbed are free of antigen. The claims are therefor drawn to new matter to the application.

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. **(New Rejection)** Claims 71-81, and 104-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims appear to be Markush type claims.

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However, the claims are indefinite in that one skilled in the art could not from the present claim language determine the scope of what is being claimed. While the claim provides a list of potential antigens, the list is introduced with the language "wherein the antigen is selected from the group comprising..." A proper Markush claim uses the language "selected from the Group consisting of..." This is because the closed language (consisting of) indicates that the claim is limited to the identified list members, whereas open language (comprising) provides no guidance as to what is or is not included within the group. Correction is required.

20. **(New Rejection)** Claims 71-81, and 104-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims each identify LnRH(GnRH) as an antigen that may be used in the claimed invention. However, it is not clear what antigen is being identified. See e.g., U.S. Patent 6559282, identifying as cancer antigen Luteinizing Hormone Releasing Hormone (LHRH) also known as Gonadotropin-releasing hormone (GnRH). Col. 11, lines 60-63. Thus, the art indicates that the Applicant may have misidentified the claimed antigen.

21. **(New Rejection)** Claims 71-81, and 104-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claim each identify antigens that may be used in the claimed compositions. However, in the listing of the antigens, the claim lists a number of viruses and microbial genera without indicating that the antigen may be from or to

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these pathogens, rather than comprising the pathogens themselves. It is therefore unclear if the antigens must comprise the target pathogen itself, or if the antigen may be antigens to the pathogen, but not necessarily comprising the antigen itself.

22. **(New Rejection)** Claims 82-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of claims 82-103 recites one of the limitations "wherein the plasmodium antigen" or "wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen." However, these claims also depend from one of claims 71-82, which indicate that the antigens of the compositions comprise the whole of the identified pathogens. Thus, there is insufficient antecedent basis for the limitations identifying specific subparticles of the pathogens as antigens.

23. **(New Rejection)** Claims 93-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on the claimed inventions wherein the antigen is a Plasmodium antigen. However, the claim is indefinite in that the claim appears to be including the S antigen (identified in the specification as a Hepatitis B antigen (page 12, lines 11-16) as one of the Plasmodium antigens that may be selected. Clarification is required.

24. **(Prior Rejection-Withdrawn)** Claims 44, 45, 50-52, 55, 60-62, 73, 74, 79-81, 84, 85, 90-92, 95, 96, 10-103, 106, 107, and 112-114 were rejected in the prior action under 35

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U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. . In view of the amendments to the claims, the rejection is withdrawn.

25. **(Prior Rejection – Withdrawn)** Claims 47 and 57 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendments to the claims, the rejection is withdrawn.

26. **(Prior Rejection – Withdrawn)** Claim 73, 74, 79-81, 84, 85, 90-92, 95, 96, 101-103, 106, 107, and 112-114 were rejected for including limitations which lack antecedent basis in the claims. Claim 73, which depends from claim 44, was treated as representative of the rejected claims. Claim 73 recited the limitation "A vaccine composition as claimed in [a prior claim], wherein the second antigen..." There was insufficient antecedent basis for the "second antigen" limitation in this claim. As the claims no longer refer to a second antigen, the rejection is withdrawn.

27. **(Prior Rejection – Withdrawn)** Claims 75-81, 86-92, 97-103, 108-114 were rejected in the prior action for including limitations that lack antecedent basis in the claims. Claim 75 was treated as representative of the rejected claims. Claim 75 recited the limitation "A vaccine composition as claimed in 46, wherein the second antigen. In view of the amendments to the claims correcting the claim language, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

28. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

29. Claim 43 is rejected under 35 U.S.C. 102(a) as being anticipated by Hauser et al., U.S. Patent 5,776,468. Claim 43 reads on a vaccine formed by the combination of an antigen with an immunostimulant adsorbed to a metallic salt. However, the claim does not specify that the metallic salt to which the immunostimulant is adsorbed is substantially free of other antigen. Hauser teaches a composition comprising an immunostimulant, a metallic salt, and an antigen. Col. 1., lines 45-53. Because the composition described by Hauser could also be formed by the process described in claims 37-41 (from which claim 43 depends), the reference anticipates the identified claim.

Allowable Subject Matter

30. Claims 32-37, 42, 44-62, 115, 116, and 118, are allowed. The subject matter of these claims appears to be free of the prior art. Although the art does teach the combination of the claimed immunostimulants and adjuvants, (see e.g. Hauser et al., U.S. Patent 5,776,468, col. 7, lines 27-39 (of record in the prior action), the art does not specifically teach adjuvant compositions wherein the antigen and immunostimulant are not bound to the same adjuvant

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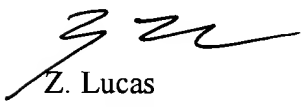
molecules. See e.g., Hauser, col. 1, lines 45-53 (teaching that the immunostimulant reacts with the alum/antigen complex to form a single complex comprising all three elements).

Conclusion

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
September 16, 2003


JAMES HOUSEL 9/22/03
SUPERVISORY PATENT EXAMINER
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